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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/602,330	06/23/2003	Clarence Nathaniel Ahlem	202.2D2	9052

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EXAMINER	
BADIO, BARBARA P	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 08/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/602,330	AHLEM ET AL.	
	Examiner	Art Unit	
	Barbara P. Badio, Ph.D.	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-28 and 80-118* is/are pending in the application.

4a) Of the above claim(s) *25-28,87,89 and 112* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *80-86,88,90-111 and 113-118* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/13/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

First Office Action on the Merits of a RCE

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 12, 2006 has been entered.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Status of the Application

3. Claims 25-28 and 80-118 are pending in the present application. Claims 25-28, 87, 89 and 112 stand withdrawn from further consideration as being drawn to a nonelected invention.

Double Patenting

4. The provisional rejection of claims 50-56, 58, 60-74 and 76-79 under the judicially created doctrine of obviousness-type double patenting over claims of

copending Application No. 10/651,515 is made moot by the cancellation of the instant claims.

Claim Rejections - 35 USC § 112

5. The rejection of claims 50-56, 58, 60-74 and 76-79 under 35 USC 112, first paragraph is made moot by the cancellation of the instant claims.

6. Claims 80-86, 88, 90-111 and 113-118 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating innate immune suppression due to radiation therapy, does not reasonably provide enablement for preventing innate immune suppression due to radiation therapy. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The instant claims are rejected for the reasons of record.

Applicant argues the evidence of record contradicts the examiner's reasoning that "the skilled artisan would have to search the prior art to find, if possible, a model for determining a person prone to innate immune suppression as defined by the present specification and, thus, in need of preventive treatment." Applicant requested under MPEP § 2144.03(c) references to support the above-mentioned statement. Applicant also refers to the present specification and US patent No. 5,461,042 for support that "innate suppression can be associated with exposure of individuals to, e.g.,

radiation....". Applicant's argument was considered but not persuasive for the following reasons.

First, MPEP § 2144 is not applicable in this instance because the rejection is not under 35 USC 103.

Second, each case is evaluated based on what is disclosed in the instant specification. Allowance of a particular issue by the Office in one case has no relevancy as to the patentability of claims in another case. ***In re Greider***, 54 USPQ 139.

Lastly, the sections of the present specification referred to applicant do not provide enablement for the "prevention" of an innate immune suppression as claimed by the instant claims. In order to prevent a response in a patient, one has to be able to determine said patient(s) that would be susceptible to such as response and, thus, would be in need of preventative measures. The present specification does not provide enablement for "prevention" because it lacks guidance to enable the skilled artisan in the art to determine a patient that would be in need of preventative therapy. Without a means of determining a patient in need of preventative therapy, the skilled artisan in the art would be unable to utilize the claimed compounds commensurate in scope with the instant claims.

For these reasons and those given in previous Office Actions, claims 80-86, 88, 90-111 and 113-118 are rejected under 35 U.S.C. 112, first paragraph.

7. The rejection of claims 50-56, 58 and 60-66 under 35 USC 112, first paragraph, as failing to comply with the written description requirement is made moot by the cancellation of the instant claims.

Claim Rejections - 35 USC § 103

8. The rejection of claims 50-56, 58, 60-74 and 76-79 under 35 USC 103 over Loria (US 5,461,042) is made moot by the cancellation of the instant claims.

9. Claims 80-86, 88, 90-111 and 113-118 are rejected under 35 U.S.C. 103(a) as being unpatentable over Loria (US 5,461,042).

The instant claims are rejected for the reasons of record.

Applicant argues the reference teaches a daily dosage of 0.2 to 30 mg/day for larger adult mammals which is lower than that recited by the instant claims. Accordingly, applicant argues the reference contains no teaching that would lead one of ordinary skill in the art to increase dosages above that expressly disclosed by the reference. Applicant also requested under MPEP § 2144.03(c) that the examiner cite references to support the allegation based on *In re Russell*. Applicant's argument was considered but not persuasive for the following reasons.

As stated in the previous Office Action, applicant is referring to the preferred dosage of the cited prior art. The cited reference states the dosages used will depend on the size and condition of the host as well as the route of administration. Thus,

although the stated dose of 0.2 to 30 mg/day is the preferred dose range, it is not limited to said doses. If applicant's argument is that the stated preferred dose range would not result in the claimed treatment, applicant needs to provide data showing that the instantly claimed doses is critical to the practice of the claimed invention.

Applicant also requested references to support the allegation based on *In re Russell*. The examiner is unsure as to what applicant needs. If applicant wants evidence that the determination of dosages and/or treatment regimen is routine in the medical art, the examiner notes that said is common knowledge (see for example, US patent No. 3,818,042, col. 3, lines 33-44; US 3,818,093, col. 3, lines 34-42; US patent No. 6,225,298, col. 4, lines 50-62; US 2006/0166946, section 0067; Goodman and Gilman, 7th edition, see for example, pages 32-33; 52-54). If addition references are needed the examiner is willing to provide it.

For these reasons and those given in the previous Office Action, claims 80-86, 88, 90-111 and 113-118 are rejected under 35 U.S.C. 103(a) as being unpatentable over Loria (US 5,461,042).

Telephone Inquiry

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Barbara P. Badio, Ph.D.
Primary Examiner
Art Unit 1617

BB
August 17, 2006